

### **TITLE 3. FOOD AND AGRICULTURE**

**NOTICE IS HEREBY GIVEN** that the Department of Food and Agriculture (Department) is proposing to take the action described in the Informative Digest. A public hearing is not scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department no later than 15 days prior to the close of the written comment period. Any person interested may present statements or arguments in writing relevant to the action proposed to the person designated in this Notice as the contact person beginning November 27, 2015 and ending at 5:00 p.m., on January 11, 2016. Following the public hearing, if one is requested, or following the written comment period if no public hearing is requested, the Department, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 407, 36601 and 36637 of the Food and Agricultural Code, and to implement, interpret or make specific sections 32912, 32912.5, 36631, 36632, and 36633 of the Food and Agricultural Code, the Department is proposing to make various changes to Title 3 of the California Code of Regulations, to read as follows:

#### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW/BENEFITS**

Existing law, section 407 of the Food and Agricultural Code, provides that the Department of Food and Agriculture (Department) may adopt such regulations as are reasonably necessary to carry out the provisions of this Code which it is directed or authorized to administer or enforce.

Existing law, section 32912 of the Food and Agricultural Code, provides that any milk or milk product that is subject to a standard of identity or standard of composition defined in Division 15 of the Food and Agriculture Code may be specially formulated or processed to lower the content of its milkfat, alter its milkfat composition, or otherwise modify its nutrient profile to the extent that it will not comply with the compositional requirements of its standard of identity or composition.

Existing law, section 32912.5 of the Food and Agricultural Code provides that any labeling requirements adopted by the Department shall be in conformity with the labeling requirements established under the Federal Food, Drug and Cosmetic Act and Title 21 of the Code of Federal Regulations.

Existing law, section 36631 of the Food and Agricultural Code, provides that the Department administer Article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, to accommodate, in a timely fashion, safe and wholesome milk products.

Existing law, section 36632 of the Food and Agricultural Code, provides that the Department may grant a temporary standard for a new milk product for an initial period of one year, following a properly noticed hearing.

Existing law, section 36633 of the Food and Agricultural Code provides that in granting a temporary standard, the Department shall establish an appropriate definition and nomenclature as well as quality and labeling requirements applicable to the permitted product.

Existing law, section 36637 of the Food and Agricultural Code states that upon granting a petition under article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, the Department shall adopt the standard as an emergency regulation pursuant to Chapter 3.5 (commencing with section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code, any regulations adopted under Article 2 of Chapter 1 of Part 3 of Division 15 of the Food and Agricultural Code shall be deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare.

The Department has in place an approved emergency regulatory action as a result of granting a petition for the approval of a temporary standard for ultra-filtered milk products. This proposal will adopt sections 450, 450.1, 450.2, 450.3, 450.4, 451 and 452 of Article 7, Chapter 1, Division 2 of Title 3 of the California Code of Regulations, to establish a standard of identity for ultra-filtered milk products permanently in regulation.

Anticipated Benefits of the Proposal: The California dairy industry generates approximately \$21 billion in direct activity and \$65 billion in dairy related activity to California's economy. This proposal benefits the dairy industry by allowing a new product into the marketplace. Encouraging innovation by allowing novel dairy products that are safe and wholesome, benefits the dairy industry and consumers as a whole.

Consistency and Compatibility with Existing State Regulations: The Department has evaluated this proposal and believes that it is not inconsistent or incompatible with existing state regulations as there were no regulations pertaining to ultra-filtered milk products. This proposal is intended to place ultra-filtered milk product standards permanently in regulation.

Document Incorporated by Reference: None.

Documents Relied Upon in Preparing Regulations:

- April 20, 2015 Petition from Tim Doelman, Senior Vice President, Operations and Product Development, fairlife, LLC, with attached copies of labels from their milk products.
- May 5, 2015, Notice of Public Hearing regarding the petition to consider the adoption of the temporary standard received from fairlife, LLC.
- Informational Brochure by the Department of Food and Agriculture, Milk and Dairy Food Safety Branch titled, "Protecting Our Dairy Products".

## **FISCAL IMPACT ESTIMATES**

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 et seq. Require Reimbursement: None

Business Impact: The Department has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This regulatory proposal is necessary to adopt the ultra-filtered milk product standards which will serve to ensure the Department fulfills its mission to serve the citizens of California by promoting and protecting a safe, healthy food supply, and enhancing local and global agricultural trade, through efficient management in accordance with Food and Agricultural Code sections 36601, 36602 and 36631.

Cost Impacts on Representative Private Persons or Businesses: The Department is not aware of any cost impacts that a representative private person or businesses would necessarily incur in reasonable compliance with the proposed action. This regulatory proposal is necessary to adopt the ultra-filtered milk product standards which will serve to ensure the Department fulfills its mission to serve the citizens of California by promoting and protecting a safe, healthy food supply, and enhancing local and global agricultural trade, through efficient management in accordance with Food and Agricultural Code sections 36601, 36602 and 36631.

Persons/Businesses affected by the proposal: Affects dairy processing plants that market milk products in interstate and intrastate commerce that want to market ultra-filtered milk products in California. It may affect distributors and retailers who market the new dairy product and may serve to promote commerce by offering a new dairy product to consumers in the marketplace. No new fees or costs are imposed by the Department as a result of this proposal upon the dairy industry. It is an option for businesses if they wish to market the new dairy product.

Effect on Housing Costs: None

Effect on Small Businesses: The Department's proposal may affect small businesses.

## **RESULTS OF ECONOMIC IMPACT ASSESSMENT**

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California. This determination is based on the fact that this proposal is only an option for businesses, if they choose to process or market ultra-filtered milk products in California. It would be a benefit to the dairy industry and might serve to expand business opportunities in the state.

The Department has made a determination that this regulatory proposal:

- Will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states by making it more costly to produce goods or services.
- Will not create or eliminate jobs or occupations. This determination is based on the fact that this proposal is only an option for businesses that may choose to process or market

ultra-filtered milk products in California. It may encourage job growth and might serve to expand business opportunities in the state.

- Does not adversely affect the creation of new businesses or the elimination of existing businesses within the State of California, and does not affect the expansion of businesses currently doing business within the State of California. This determination is based on the fact that this proposal is only an option for businesses, if they choose to process or market ultra-filtered milk products in California. It would be a benefit to the industry and might serve to expand business opportunities in the state.
- Does not impact multiple industries.
- Does not adversely impact human health, worker safety, or the State's environment. The Department has no specific health and safety concerns with the standards of identity for ultra-filtered milk products as specified in this proposal. This is because the standards require that ultra-filtered milk products must be labeled in accordance with applicable provisions of Title 21 of the Code of Federal Regulations. Additionally, manufacturers of ultra-filtered milk products must comply with all existing licensing and inspection requirements enforced by the Milk and Dairy Food Safety Branch as well as food safety and sanitary processing requirements and standards applicable to other market milk products. The Department's Milk and Dairy Food Safety Branch is charged with the mission of ensuring that all milk and milk products are safe and wholesome that are marketed to California consumers are safe and wholesome.
- Affects dairy processing plants that market milk products in interstate and intrastate commerce that want to market ultra-filtered milk products in California. It may affect distributors and retailers who market the new dairy product and may serve to promote commerce by offering a new dairy product to consumers in the marketplace. No new fees or costs are imposed by the Department as a result of this proposal upon the dairy industry. It is an option for businesses if they wish to market the new dairy product.
- Serves to promote and encourage innovation by allowing into the marketplace a new dairy product category which is produced by a novel technology.

This initial determination is based on the fact that the proposed regulation imposes no new fees or costs to the dairy industry and allows a new milk product to be sold to California consumers that is safe and wholesome. This regulatory proposal is necessary to adopt the ultra-filtered milk product standards which will serve to ensure the Department fulfills its mission to serve the citizens of California by promoting and protecting a safe, healthy food supply, and enhancing local and global agricultural trade, through efficient management in accordance with Food and Agricultural Code sections 36601, 36602 and 36631.

Occupations/Businesses Impacted: The Department has made an initial determination that this regulatory proposal may impact occupations or businesses. However, this proposal is only an option for businesses, if they choose to process or market ultra-filtered milk products in California. It would be a benefit to the dairy industry and might serve to expand business opportunities in the state.

Business Reporting Requirement: The regulation does not require a report, which shall apply to businesses.

Comparable Federal Regulations: This proposal does not duplicate or conflict with federal regulations as there are no standards of identity for ultra-filtered milk products in federal regulations. However, all milk product labels must conform to the federal requirements as specified in Title 21 of the Code of Federal Regulations, in addition to the labeling requirements as specified in applicable California statutes and regulations.

### **CONSIDERATION OF ALTERNATIVES**

The Department must determine that no reasonable alternative considered or that has otherwise been identified and brought the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This regulatory proposal is necessary to adopt the ultra-filtered milk product standards which will serve to ensure the Department fulfills its mission to serve the citizens of California by promoting and protecting a safe, healthy food supply, and enhancing local and global agricultural trade, through efficient management in accordance with Food and Agricultural Code sections 36601, 36602 and 36631.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the hearing (if a hearing is requested) or during the written public comment period.

### **INITIAL STATEMENT OF REASONS AND INFORMATION**

The Department has prepared an initial statement of reasons for the proposed action and has available all the information upon which the proposal is based.

### **TEXT OF PROPOSAL**

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all the information upon which the proposal is based, may be obtained by contacting the persons named below or by accessing the Department of Food and Agriculture's website as indicated below in this Notice.

### **AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE**

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the persons named below.

Any person may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact persons named below or by accessing the website listed below.

### **CONTACT PERSONS**

Inquiries concerning the substance of the proposed regulations, or any written comments concerning this proposal are to be addressed to the following:

Anne Quilter, Fluid Milk Testing Coordinator  
Department of Food and Agriculture  
Milk and Dairy Food Safety Branch  
1220 N Street  
Sacramento, CA 95814  
Telephone: (916) 900-5079  
E-mail: [anne.quilter-goldstein@cdfa.ca.gov](mailto:anne.quilter-goldstein@cdfa.ca.gov)

The back-up contact person is:

Nancy Grillo, Regulation Coordinator  
Department of Food and Agriculture  
Animal Health & Food Safety Services  
1220 N Street  
Sacramento, CA 95814  
Telephone (916) 900-5033  
E-mail: [nancy.grillo@cdfa.ca.gov](mailto:nancy.grillo@cdfa.ca.gov)

Website Access: Materials regarding this proposal can be found by accessing the following  
Internet address: <http://www.cdfa.ca.gov/ahfss/regulations.html>